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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,661	05/26/2000	JEAN-PIERRE SACHETTO		6789

2292 7590 01/27/2003

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EXAMINER

DEWITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

9,11, 23, 27, 35, 38, 39

Office Action Summary

Application No.

09/508,661

Applicant(s)

SACHETTO ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-15 and 22-52 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 and 23-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-4, 6, 8-15, 22-52 are pending in the instant application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 6, 15, 22-28, 42-52 drawn to a delayed release oral pharmaceutical composition, classified in class 424, subclass 479.
- II. Claims 8, 9-14, 29-41, drawn to a rectally administrable pharmaceutical composition, classified in class 514, subclass 772.

2. The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions, and modes of operation. Group I being drawn to a delayed release formulation which is a pharmaceutical composition which can be orally taken, as compared with the rectally administrable composition which is administered through the rectum.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

3. Newly submitted claims 29-41, and dependent, amended claims 8-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 29 is directed to a pharmaceutical composition that is administered rectally, as opposed to the delayed release oral (DRO) composition which is administered orally.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 29-52, and 8-15 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 4, 6, 15, 22-28, and 42-52 are rejected under 35 U.S.C. 103 as made obvious by Savastano et al. (U.S. Pat. No. 5,681,584).

Savastano relates to a drug delivery device for delivering a drug to a pre-selected region of the gastro-intestinal tract. Savastano teaches that delivery of a beneficial drug in the colon would be beneficial for a variety of diseases including inflammatory bowel disease (col. 1, lines 34-42). The solid core of the drug delivery device can include binders such as xanthan gum (col. 7, lines 48-50 and 18). Further, the drug delivery can include a semi-permeable membrane such as hydropropylmethylcellulose (HPMC) (col. 10, lines 17-31). As seen in the examples, the amount of HPMC used would meet the therapeutically effective amount (col. 13, lines 5). Savastano does not teach the device as being DRO (delayed release oral), however, the devices are time-controlled to release active agent. One with ordinary skill in the art would equate DRO with time-controlled release, thus the invention is obvious.

5. Claims 1-3, 4, 6, and 22-28 are rejected under 35 U.S.C. 103 as being made obvious by Ulmius (U.S. Pat. No. 5,643,602).

Ulmius teaches an oral pharmaceutical composition for targeted slow release in

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the treatment of inflammatory bowel diseases. The unit (composition) consists of a core, a first layer on the core, and a second layer on the first layer. The first layer can consist of polymers such as hydroxypropylmethylcellulose (col. 5, lines 5-20). Ulmius does not refer to the composition as DRO delayed-release oral, however the compositions are targeted slow-release. One with ordinary skill in the art would have equated DRO with slow-release, thus the invention is obvious.

6. Claims 1, 3, 6, 22 are rejected under 35 U.S.C. 103 as being made obvious by Theeuwes et al. (U.S. Pat. No. 4,904,474).

Theeuwes is drawn to the delivery of a beneficial drug to a region of the gastrointestinal tract. Theeuwes teaches that the delivery of a beneficial drug in the colon is therapeutically indicated for the treatment of inflammatory bowel disease. (col. 1, lines 15-17). Means for using the composition comprises delaying the release of the drug from the delivery device as the delivery device passes through the small intestine (col. 6, lines 46-50). The compositions include polymeric compositions, such as hydroxypropylmethylcellulose (col. 7, lines 1-2). Theeuwes does not describe the delivery of the drug as DRO, however as stated Theeuwes does teach a means for delaying the release of the drug from the device. One with ordinary skill in the art would have equated this means with DRO, thus the invention is made obvious.

Response to Arguments

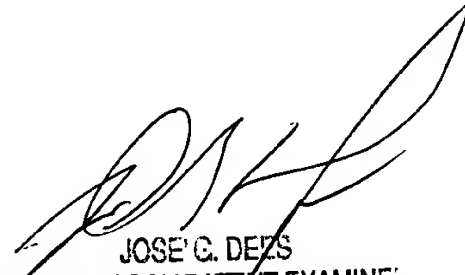
7. In view of Applicant's amendments and response to the office action mailed 4/23/01, the previous rejections are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

RMD
January 25, 2003


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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